DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 26, 2014

Osstem Implant Co. Ltd.
% Patrick Lim
QA/RA Manager, Hiossen Inc.
85 Ben Fairless Drive
FAIRLESS HILLS, PA 19030

Re: K141497
Trade/Device Name: Portable X-Ray System (Model: EXARO, Xray2GO)
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral Source X-ray System
Regulatory Class: II
Product Code: EHD
Dated: July 25, 2014
Received: July 28, 2014

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K141497/S001

Device Name: Portable X-ray System (Model: EXARO, Xray2GO)

Indications for Use: The Portable X-ray system (Model: EXARO, Xray2GO) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign-Off)
Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

510(k): K141497/S001

Section 009

OSSTEM Implant Co., Ltd.

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Tel: +82 70-4394-5029 Fax: +82 51 850-4341 www.osstem.com

510K Summary

Portable X-Ray System / Model : EXARO, Xray2GO

1. Company and Correspondent Making the Submission

Submitter :	OSSTEM Implant Co,.Ltd.
Address :	301ho, Korea Electronics Cooperation B/D 114 Gasandigital2ro, Geumcheon-gu, Seoul-si, Korea 153-803
Tel :	82-70-4394-5029
Fax :	82-2-863-3479
E-mail :	qa@osstem.com
Contact :	Mr. Mooyong Park

2. US Agent for FDA Contact :

Name :	HIOSSEN Inc.,
Address :	85 Ben Fairless Dr. Fairless Hills, PA 19030 USA
Contact :	Patrick Lim, QA/RA manager.
Telephone No.:	888-678-0001
Fax No.:	267-759-7004
Email:	dtlim@osstem.com

3. Device Information

Proprietary/Trade Name:	Portable X-Ray System (Model: EXARO, Xray2GO)
Common/Usual Name:	Portable X-Ray System
Classification Name:	Extraoral Source X-Ray System
Product Code:	EHD
Device Class:	Class II per regulation 21 CFR 872.1800

4. Equivalent Legally Marketed Device

K number:	K122124
Proprietary/Trade Name:	Portable X-Ray System(Model:EXARO)
Common/Usual Name:	Portable X-Ray System
Classification Name:	Extraoral Source X-Ray System
Product Code:	EHD
Device Class:	Class II per regulation 21 CFR 872.1800

5. Date Prepared: 6/4/2014

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6. Description of the Device

EXARO, Xray2GO, a portable dental X-ray system, operates on 25.2V DC supplied by a rechargeable Li-Polymer battery pack, The X-ray tube head, controls and power source are assembled into a single hand-held enclosure. The package includes a battery charger.
The potable X-ray system, EXARO, Xray2GO, being composed of X-ray generator, controller, and beam limiting device is designed to diagnose tooth and jaw through generated and controlled X-ray. The operating principle of EXARO, Xray2GO starts from the generation of X-ray by high voltage electricity, which in turn penetrates tooth and jaw area after flowing through X-ray tube and produces X-ray images on X-ray receptors (i.e. chemical film or digital sensor)
This device contains a high frequency inverter that converts direct to alternating current, X-ray tube head, electrical protective devices, and other elements. The EXARO, Xray2GO produces sharp and clear images and prevents patients and dentists from radiation exposure with utilizing small dose of radiation.

A list of modifications made to the subject device is below:

Characteristic		Proposed OSSTEM Implant Co,. Ltd. EXARO, Xray2GO	Predicate OSSTEM Implant Co,. Ltd. EXARO
510(k) number		Not assigned yet	K122124
Anode current		3mA	2mA
Expose time		0.01~1.6 seconds, 0.01 increments	0.01~2.0 seconds, 0.01 increments
Battery	Battery part No.	SPB605060H4	JBL7451251700100FJ
	Battery Current	Current : 12.0CmA	Current : 1.0CmA
	Battery Max. Current	Max. current : 1900mAh	Max. current : 950mAh
Battery case size		87 x 111.9 x 42H (mm)	87 x 111.9 x 36H (mm)

7. Indications for use (Intended Use)

The Portable X-ray System (Model: EXARO, Xray2GO) is intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.

8. Safety, EMC and Performance Data

No additional testing was added for this submission based on the modifications.

9. Safety and Effectiveness, comparison to Predicate

The result of bench and clinical evaluation indicates that the new device is as safe and effective as the predicate devices.

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10. Substantial Equivalence Chart

	NEW	Predicate Device
Manufacturer	OSSTEM IMPLANT Co,. Ltd.	OSSTEM IMPLANT Co,. Ltd.
Model	EXARO, Xray2GO	EXARO
510(k) Number	Not assigned yet	K122124
Energy Source	Rechargeable 25.2V, DC Lithium Polymer Battery pack	Rechargeable 25.2V, DC Lithium Polymer Battery pack
Expose Time	0.01~1.6 seconds, 0.01 increments	0.01~2.0 seconds, 0.01 increments
Time Accuracy	±(10%+1ms)	±(10%+1ms)
Heat Capacity	8.5 KHU	8.5 KHU
Power Output	100W	100W
mA	3mA Fixed	2mA Fixed
kVp	60kV Fixed	60kV Fixed
Focal Spot	0.8mm	0.8mm
Wave Form	Constant Potential (DC)	Constant Potential (DC)
Safety, EMC and Performance	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-7, IEC 60601-2-28, IEC 60601-2-32
Source to skin Distance	20cm	20cm
Cone Diameter	6cm	6cm
User Interface	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.	Exposure time: up, down. Selection buttons of parts of teeth, adult and child, film and sensor with display.
Exposure switch	Control panel and remote controller	Control panel and remote controller
Tubehead Mounting	Yes	Yes
Principle of Operation	X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor)	X-ray generated by high voltage electricity into X-ray tube, which penetrates hand, tooth and jaw, and makes X-ray images on receptor (Chemical Film or Digital Sensor)
Intended Use	intended to be used by trained dentists and dental technicians as extra-oral x-ray source for producing diagnostic x-ray images using intra-oral image receptors or film. Its use is intended for both adult and pediatric subjects.	

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The subject and predicate devices are similar in indications, design, technology, functions, and principle of operation.
The differences between two devices are anode current, expose time, battery (part no., current, and maximum current) and battery case size.
Any differences do not raise different questions of safety and effectiveness than the predicate. Therefore, there is no difference between the subject and predicate with respect to the indications or technology.

11. Conclusion

In reference to the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 807 and the comparison information provided substantial equivalent chart above, the OSSTEM IMPLANT Co., Ltd., believes that the portable X-ray system (Model: EXARO, Xray2GO) is substantially equivalent to its predicate device.